K992508

AUG 19 1999

510(k) Summary per 21 CFR § 807.92

Instruments for Medicine and Diagnostics, Inc. (a.k.a. I4MD)
3959 West 1820 South
Salt Lake City, Utah 84104
(801) 972-0500
(801) 972-4884 (fax)
Tracy S. Best, Regulatory Manager
Preparation Date: July 19, 1999

Summary of Safety and Effectiveness for:

Trade Name: TSX Probe

Common Name: Laser Delivery Device, Ocular Contact Probe

Classification Name: Laser, Ophthalmic, Accessory

Legally Marketed Predicate Devices for Substantial Equivalence:

* Iris G-Probe, Manufactured by Iriderm Division, Laser Instrument, Surgical, Powered

Rationale for SE:

The Iris G-Probe is a sterile single use delivery device for the reduction of intra ocular pressure (IOP) in glaucoma patients. A three meter, 600 μm fiber delivers the light energy from the laser to the focusing lens. The g-probe is furnished as sterile to the customer. The treatment performed using this non-invasive contact probe allows for selective ablation of ciliary processes. The procedure, Transscleral Cyclophotocoagulation (CYC), causes less postoperative pain and inflammation and is an alternative treatment from Cyclocryotherapy. The device is compatible with infrared photocoagulators.

Description of Submitted Device:

The TSX Probe consists of three basic parts; handgrip, tip and focusing lens and is a pre-sterilized (Ethylene Oxide) disposable contact probe. Its tip is a clear amber medical plastic that is angled to match the curvature of the human eye and therefore allows for the placement of the probe vertically, closest to the limbus. The angle of the contact tip (distal end) conforms to the curvature of the eye. The three-meter 600 μm fiber plugs into an HGM SmartScan™ laser or other SMA connection compatible devices. The device allows the physician to perform non-invasive contact CYC with marketed (approved) infrared lasers.

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Intended Uses of the TSX Probe:

See attachment "5" for a complete listing of indicated uses.

Technological Characteristics and Substantial Equivalence:

The TSX Probe is similar to the G-Probe, both have a 600 μm fiber which delivers the treatment light to the tip of the contact probe. The TSX Probe is sleeker having a contact tip which is smaller than the G-Probe. Both offer treatment modalities for laser light delivery to ocular tissue, for various types of glaucoma in it's advanced stages. The probes are moved in a circular fashion around the cornea using the limbus as a circular guide. Both probes allow laser energy to be fired at regular intervals into the ciliary body. The two probes are similar in design, intended use, and compatible with lasers widely in use.

Conclusion:

The TSX Probe is substantially equivalent to other existing laser surgical delivery devices already in commercial distribution. The labeling of the TSX Probe as a single-use pre-sterilized delivery device for treatment of (CYC) is an addition to a large field of Ophthalmic treatment methods with medical lasers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1999

Mr. Tracy S. Best
Regulatory Affairs
Instruments for Medicine and Diagnostics, Inc.
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K992508
Trade Name: TSX Probe
Regulatory Class: II
Product Code: GEX
Dated: July 19, 1999
Received: July 27, 1999

Dear Mr. Best:

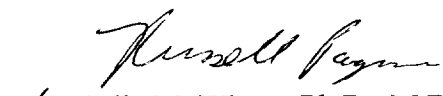
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992508

Device Name: TSX Probe

Indications For Use:

Contact Transscleral Cyclophotocoagulation (CYC) for the reduction of intra ocular pressure (IOP) in glaucoma patients. This ocular contact probe to be used with approved infrared laser devices for this procedure.

Ablation of the Ciliary Body in glaucoma patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Russell Cayou for JRS

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992508

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)